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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ung-Chhun et al.
Appl. No.: 10/678,875
Conf. No.: 1282
Filed: October 3, 2003
Title: METHOD FOR PRODUCING IMPROVED MEDICAL DEVICES AND DEVICES SO PRODUCED
Art Unit: 3738
Examiner: Hieu Phan
Docket No.: 112713-638

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.56, 37 C.F.R. 1.97, and 37 C.F.R. 1.98, Applicants request that a citation and examination of the references cited below, and on the attached PTO-1449 form, copies of which can be found in the parent, application no. 09/790,395, filed on February 21, 2001, be made during the course of examination of the above-identified application for United States patent.

### U.S. PATENT DOCUMENTS

| Patent Number | Inventor | Date |
|---|---|---|
| 3,945,926 | Kesting | 3/23/76 |
| 4,053,420 | Marx | 11/77 |
| 4,130,642 | Kikygawa et al. | 12/19/78 |
| 4,256,588 | Hoehn et al. | 3/81 |
| 4,283,289 | Meyst et al. | 8/81 |
| 4,330,410 | Takenaka et al. | 5/18/82 |
| 4,358,476 | Zimmer et al. | 11/9/82 |
| 4,399,035 | Nohmi et al. | 8/16/83 |
| 4,416,777 | Kuroda et al. | 11/22/83 |
| 4,596,657 | Wisdom | 6/24/86 |
| 4,618,533 | Steuck | 10/86 |

02/24/2005 HMARZI1 00000021 10678875 180.00 OP
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02/24/2005 HMARZI1 00000021 10678875
01 FC:1806 180.00 OP

| | | |
|---|---|---|
| 4,675,361 | Ward, Jr. | 06/23/87 |
| 4,701,267 | Watanabe et al. | 10/20/87 |
| 4,767,541 | Wisdom | 8/30/88 |
| 4,810,378 | Carmen et al. | 3/7/89 |
| 4,840,851 | Gölander et al. | 06/20/89 |
| 4,855,063 | Carmen et al. | 8/8/89 |
| 4,880,548 | Pall et al. | 11/14/89 |
| 4,915,848 | Carmen et al. | 4/10/90 |
| 4,917,799 | Masuda et al. | 4/17/90 |
| 4,919,823 | Wisdom | 4/24/90 |
| 4,925,572 | Pall | 5/15/90 |
| 4,936,993 | Nomura | 6/26/90 |
| 4,936,998 | Nishimura et al. | 6/26/90 |
| 4,943,287 | Carmen | 7/24/90 |
| 4,976,861 | Pall | 12/90 |
| 4,985,153 | Kuroda et al. | 1/15/91 |
| 4,977,577 | Stewart | 3/91 |
| 5,034,135 | Fischel | 7/23/91 |
| 5,089,146 | Carmen et al. | 2/92 |
| 5,092,996 | Spielberg | 3/92 |
| 5,100,551 | Pall et al. | 3/92 |
| 5,100,564 | Pall et al. | 3/92 |
| 5,104,788 | Carmen et al. | 4/92 |
| 5,128,048 | Stewart et al. | 7/92 |
| 5,190,657 | Heagle et al. | 3/93 |
| 5,194,145 | Schoendorfer | 3/16/93 |
| 5,229,012 | Pall et al. | 7/93 |
| 5,252,222 | Matkovish et al. | 10/93 |
| 5,258,126 | Pall et al. | 11/93 |
| 5,258,127 | Gsell et al. | 11/93 |
| 5,647,985 | Ung-Chhun et al. | 7/15/97 |

| | | |
|---|---|---|
| 5,795,483 | Ung-Chhun et al. | 8/18/98 |

## FOREIGN PATENT DOCUMENTS

| Patent Number | Country | Publication Date |
|---|---|---|
| 0 370 584 | Europe | 5/3/90 |
| 03000 074 | Japan | 12/88 |
| 0 397 403 | Europe | 11/14/90 |
| 58983/90 | Australia | 1/91 |
| 0 406 485 | Europe | 1/91 |
| 0 408 462 | Europe | 1/91 |
| 0 419 346 | Europe | 3/27/91 |
| 0 500 472 | Europe | 9/93 |
| 0 561 379 | Europe | 9/93 |
| 05034337 | Japan | 7/91 |
| 05087808 | Japan | 9/91 |
| 05148150 | Japan | 11/91 |
| 05148151 | Japan | 11/91 |
| 4-187206 | Japan | 7/92 |
| 5-194243 | Japan | 3/93 |
| 9308904 | PCT | 5/93 |
| 9303740 | PCT | 7/93 |

## OTHER REFERENCES


Grimm et al., "Glutaraldehyde Affects Biocompatibility of Bioprosthetic Heart Valves," *Surgery,* 1992; Vol. 111, No. 1:74-78.

Golomb et al., "The Role of Glutaraldehyde-induced Cross-links in Calcification of Bovine Pericardium Used in Cardiac Valve Bioprostheses," *Amer. J. Pathol.,* 1987; Vol. 127, No. 1:122- 130.

Levy et al., "Cardiovascular Implant Calcification: a Survey and Update," *Biomaterials,* 1991; Vol. 12:707-714.

Harasym et al., "Poly(ethylene glycol)-Modified Phospholipids Prevent Aggregation during Covalent Conjugation of Proteins to Liposomes," *Bioconjugate Chem.*, 1995; Vol. 6, No. 2:187- 194.

Chen et al., "Effect of 2-amino Oleic Acid Exposure Conditions on the Inhibition of Calcification of Glutaraldehyde Cross-linked Porcine Aortic Valves," J. *Biomed. Mater. Res.*, 1994; Vol. 28:1485-1495.

O'Brien et al., "The Metronic Intact Xenograft: an Analysis of 342 Patients over a Seven-year Follow-up Period," *Ann. Thorac Surg.*, 1995; Vol. 60(Suppl.):S253-5257.

Breillatt et al., "Recombinant Hirudin Analog Designed for Attachment to Polymers," Abstract FASEB J., 1992, Vol. 6:A-1320.

Gendler et al., "Toxic reactions evoked by glutaraldehyde-fixed pericardium and cardiac valve tissue bioprosthesis," Journal of Biomedical Materials Research, 1984, Vol. 18: 727-736.

Park et al., "Chemical Modification of Implantable Biologic Tissue for Anti-Calcification," ASAIO Journal, 1994, Vol. 40: M377-M382.

Han et al., "In Vivo Biostability and Calcification-Resistance of Surface-Modified PU-PEO-SO3," Journal of Biomedical Materials Research, 1993, Vol. 27: 1063-1073.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

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BY _____

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Dated: February 17, 2005

| TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c)) | Docket No. 112713-638 |
|---|---|

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PATENT & TRADEMARK FEB 22 2005

In Re Application Of: **Ung-Chhun et al.**

| Application No. | Filing Date | Examiner | Customer No. | Group Art Unit | Confirmation No. |
|---|---|---|---|---|---|
| 10/678,875 | October 3, 2003 | Hieu Phan | 29200 | 3738 | 1282 |

Title: **METHOD FOR PRODUCING IMPROVED MEDICAL DEVICES AND DEVICES SO PRODUCED**

Address to:
**Commissioner for Patents**
**P.O. Box 1450**
**Alexandria, VA 22313-1450**

**37 CFR 1.97(b)**

1. ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

   ☐ the statement specified in 37 CFR 1.97(e);

   **OR**

   ☒ the fee set forth in 37 CFR 1.17(p).

| TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c)) | Docket No. 112713-638 |
|---|---|

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In Re Application: Ung-Chiang et al.

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|---|---|---|---|---|---|
| 10/678,875 | October 3, 2003 | Hieu Phan | 29200 | 3738 | 1282 |

Title: METHOD FOR PRODUCING IMPROVED MEDICAL DEVICES AND DEVICES SO PRODUCED

**Payment of Fee**

**(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))**

☒ A check in the amount of **$180.00** is attached.

☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.

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- ☒ Credit any overpayment.
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☐ Payment by credit card. Form PTO-2038 is attached.

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**February 17, 2005**

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*Signature of Person Mailing Correspondence*

**Heather Foster**

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Dated: **February 17, 2005**

*Signature*

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cc:

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# INFORMATION DISCLOSURE CITATION

*(Use several sheets if necessary)*

| ATTY DOCKET NO. | SERIAL NO. |
|---|---|
| 112713-638 | 10/678,875 |
| Ung-Chhun et al. | |
| FILING | GROUP |
| 10/03/2003 | 3738 |

## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---|---|---|---|---|---|---|---|
| | A1 | 3,945,926 | 3/23/76 | Kesting | | | |
| | A2 | 4,053,420 | 11/77 | Marx | | | |
| | A3 | 4,130,642 | 12/19/78 | Kikygawa et al. | | | |
| | A4 | 4,256,588 | 3/81 | Hoehn et al. | | | |
| | A5 | 4,283,289 | 8/81 | Meyst et al. | | | |
| | A6 | 4,330,410 | 5/18/82 | Takenaka et al. | | | |
| | A7 | 4,358,476 | 11/9/82 | Zimmer et al. | | | |
| | A8 | 4,399,035 | 8/16/83 | Nohmi et al. | | | |
| | A9 | 4,416,777 | 11/22/83 | Kuroda et al. | | | |
| | A10 | 4,596,657 | 6/24/86 | Wisdom | | | |
| | A11 | 4,618,533 | 10/86 | Steuck | | | |

## FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES | TRANSLATION NO |
|---|---|---|---|---|---|---|---|---|
| | A12 | 0 370 584 | 5/3/90 | Europe | | | | |
| | A13 | 03000 074 | 12/88 | Japan | | | | |
| | A14 | 0 397 403 | 11/14/90 | Europe | | | | |
| | A15 | 58983/90 | 1/91 | Australia | | | | |
| | A16 | 0 406 485 | 1/91 | Europe | | | | |

## OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | | |
|---|---|---|---|
| | | A17 | Grimm et al., "Glutaraldehyde Affects Biocompatibility of Bioprosthetic Heart Valves," Surgery, 1992, Vol. 111, No. 1:74-78. |
| | | A18 | Golomb et al., "The Role of Glutaraldehyde-induced Cross-links in Calcification of Bovine Pericardium Used in Cardiac Valve Bioprostehses," Amer. J. Pathol., 1987, Vol. 127, No. 1:122-130. |

| EXAMINER | DATE CONSIDERED |
|---|---|
| | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|---|---|
| 112713-638 | 10/678,875 |
| Ung-Chhun et al. | |
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## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---|---|---|---|---|---|---|---|
| | B1 | 4,675,361 | 6/23/87 | Ward, Jr. | | | |
| | B2 | 4,701,267 | 10/20/87 | Watanabe et al. | | | |
| | B3 | 4,767,541 | 8/30/88 | Wisdom | | | |
| | B4 | 4,810,378 | 3/7/89 | Carmen et al. | | | |
| | B5 | 4,840,851 | 6/20/89 | Golander et al. | | | |
| | B6 | 4,855,063 | 8/8/89 | Carmen et al. | | | |
| | B7 | 4,880,548 | 11/14/89 | Pall et al. | | | |
| | B8 | 4,915,848 | 4/10/90 | Carmen et al. | | | |
| | B9 | 4,917,799 | 4/17/90 | Masuda et al. | | | |
| | B10 | 4,919,823 | 4/24/90 | Wisdom | | | |
| | B11 | 4,925,572 | 5/15/90 | Pall | | | |

## FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES | TRANSLATION NO |
|---|---|---|---|---|---|---|---|---|
| | B12 | 0 408 462 | 1/91 | Europe | | | | |
| | B13 | 0 419 346 | 3/27/91 | Europe | | | | |
| | B14 | 0 500 472 | 9/93 | Europe | | | | |
| | B15 | 0 561 379 | 9/93 | Europe | | | | |
| | B16 | 05034337 | 7/91 | Japan | | | | |

## OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | | |
|---|---|---|---|
| | | B17 | Levy et al., "Cardiovascular Implant Calcification: A Survey and Update," Biomaterials, 1991, Vol. 12: 707-714. |
| | | B18 | Harasym et al., "Poly(ehtylene glycol)-Modified Phospholipids Prevent Aggregation during Covalent Conjugation of Proteins to Lipsomes," Bioconjugate Chem., 1995, Vol. 6, No. 2: 187-194. |

| EXAMINER | DATE CONSIDERED |
|---|---|
| | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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*(Use several sheets if necessary)*

| ATTY DOCKET NO. | SERIAL NO. |
|---|---|
| 112713-638 | 10/678,875 |
| **Ung-Chhun et al.** | |
| FILING | GROUP |
| 10/03/2003 | 3738 |

## U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---|---|---|---|---|---|---|---|
| | C1 | 4,936,993 | 6/26/90 | Nomura | | | |
| | C2 | 4,936,998 | 6/26/90 | Nishimura et al. | | | |
| | C3 | 4,943,287 | 7/24/90 | Carmen | | | |
| | C4 | 4,976,861 | 12/90 | Pall | | | |
| | C5 | 4,985,153 | 1/15/91 | Kuroda et al. | | | |
| | C6 | 4,977,577 | 3/91 | Stewart | | | |
| | C7 | 5,034,135 | 7/23/91 | Fischel | | | |
| | C8 | 5,089,146 | 2/92 | Carmen et al. | | | |
| | C9 | 5,092,996 | 3/92 | Spielberg | | | |
| | C10 | 5,100,551 | 3/92 | Pall et al. | | | |
| | C11 | 5,100,564 | 3/92 | Pall et al. | | | |

## FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES | TRANSLATION NO |
|---|---|---|---|---|---|---|---|---|
| | C12 | 05087808 | 9/91 | Japan | | | | |
| | C13 | 05148150 | 11/91 | Japan | | | | |
| | C14 | 05148151 | 11/91 | Japan | | | | |
| | C15 | 4-187206 | 7/92 | Japan | | | | |
| | C16 | 5-194243 | 3/93 | Japan | | | | |

## OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | | |
|---|---|---|---|
| | | C17 | Chen et al., "Effect of 2-amino Oleic Acid Exposure Conditions on the Inhibition of Calcification of Glutaraldehyde Cross-Linked Porcine Aortic Valves," J. Biomed. Mater. Res., 1994, Vol. 28: 1485-1495. |
| | | C18 | O'Brien et al., "The Metronic INtact Xenograft: An Analysis of 342 Patients over a Seven-Year Follow-up Period," Ann. Thorac. Surg., 1995, Vol. 60 (Suppl.): S253-S257. |

| EXAMINER | DATE CONSIDERED |
|---|---|
| | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.


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|---|---|
| 112713-638 | 10/678,875 |
| Ung-Chhun et al. | |
| FILING | GROUP |
| 10/03/2003 | 3738 |

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| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---|---|---|---|---|---|---|---|
| | D1 | 5,104,788 | 4/92 | Carmen et al. | | | |
| | D2 | 5,128,048 | 7/92 | Stewart et al. | | | |
| | D3 | 5,190,657 | 3/93 | Heagle et al. | | | |
| | D4 | 5,194,145 | 3/16/93 | Schoendorfer | | | |
| | D5 | 5,229,012 | 7/93 | Pall et al. | | | |
| | D6 | 5,252,222 | 10/93 | Matkovish et al. | | | |
| | D7 | 5,258,126 | 11/93 | Pall et al. | | | |
| | D8 | 5,258,127 | 11/93 | Gsell et al. | | | |
| | D9 | 5,647,985 | 7/15/97 | Ung-Chhun et al. | | | |
| | D10 | 5,795,483 | 8/18/98 | Ung-Chhun et al. | | | |
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## FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES | TRANSLATION NO |
|---|---|---|---|---|---|---|---|---|
| | D11 | 93/08904 | 5/93 | PCT | | | | |
| | D12 | 93/03740 | 7/93 | PCT | | | | |
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## OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | | |
|---|---|---|---|
| | | D13 | Breillatt et al., "Recombinant Hirudin Analog Designed for Attachment to Polymers," Abstract FASEB J., 1992, Vol. 6, A-1320. |
| | | D14 | GEndler et al., "Toxic Reactions Evoked by Glutaraldehyde-fixed Pericardium and CardiacValve Tissue Bioprosthesis," Journal of Biomedical Materials Rsearch, 1984, Vol. 18: 727-736. |

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|---|---|
| | |

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## OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

| | | | |
|---|---|---|---|
| | | E1 | **Park et al., "Chemical Modification of Implantable Biologic Tissue for Anti-Calcification," ASAIO Journal, 1994, Vol. 40: M377-M382.** |
| | | E2 | **Han et al., "In Vivo Biostability and Calcification-Resistance of Surface-Modified PU-PEO-SO3," Journal of Biomedical Materials Research, 1993, Vol. 27: 1063-1073.** |

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